



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: September 12, 2017

Subject: Efficacy Review for Excelyte Vet, EPA Reg. No. 92108-1
(DP Barcode: 440982)

From: Alison Clune
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Thru: Mark Perry, Team Leader
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Applicant: Paradigm Convergence Technologies Corp.
4325 Commerce St.
Little River, SC 29566

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Hypochlorous acid	0.046%
<u>Other Ingredients</u>	<u>99.954%</u>
Total.....	100.000%

I BACKGROUND

Product Description (as packaged, as applied): Ready-to-use liquid prepared within 30 days of use, liquid and spray applications

Submission type: Label amendment

Currently registered efficacy claim(s): one-step hospital disinfectant (bactericidal, virucidal, tuberculocidal, sporicidal for *Clostridium difficile*) and food and non-food contact surface sanitizer for use on hard, non-porous surfaces.

Requested action(s): Add virucidal disinfection claims and update label language to include claims accepted for a “sister” product, EcaFlo Anolyte (EPA Reg. No. 82341-1).

Documents considered in this review:

- 2 letters from applicant to EPA dated May 12, 2017 and July 14, 2017
- Proposed label dated 9/1/2017
- 2 efficacy studies (MRID 50288201, later changed to MRID 50390001, and 50288202)
- Revised Certificate of Analysis for Lots 112315-1 and 112315-2 dated November 23, 2015
- 1 letter from Microchem Laboratory to EPA dated July 17th, 2017 supporting the revised Certificate of Analysis
- 1 letter from Microchem Laboratory to EPA dated August 23, 2017 confirming that the 10 minute test contact time on page 9 was a typographical error in MRID 50288201
- Data Matrix (EPA Form 8570-35) dated 05/12/2017
- Accepted basic Confidential Statement of Formula (EPA Form 8670-4) dated 08/15/2013.

II PROPOSED DIRECTIONS FOR USE

“To [Clean and] Disinfect [and Deodorize] Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply [Wipe, Spray or Dip] Excelyte® VET at 500 ppm FAC to hard, non-porous surfaces with a cloth, wipe, mop or sponge. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry...”

III STUDY SUMMARIES

1.	MRID	50390001	Study Completion Date:	1/6/16			
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Bovine Viral Diarrhea Virus, Strain NADL (ATCC VR-1422)					
Test Method		ASTM E1053-11					
Application Method		Liquid					
Test Substance Preparation	Name/ID	EcaFlo Anolyte					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	112315-1, 112315-2					
	Preparation	Tested concentration: LCL Dilution: Ready-to-use Diluent: NA					
Soil load		OECD 3-part soil load					
Carrier type, # per lot		Glass petri dishes, 2					
Test conditions		Contact time	2 minutes	Temp	27-27.5°C	RH	45%
Testing Lab, Lab Study ID		Antimicrobial Test Laboratories, GLP1344					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Carrier dry temperature: 9.2-10.0°C					

2.	MRID	50288202	Study Completion Date:		1/12/16		
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Influenza A (H1N1), Strain A/Virginia/ATCC1/2009 (ATCC VR-1736)					
Test Method		ASTM E1053-11					
Application Method		Liquid					
Test Substance Preparation	Name/ID	EcaFlo Anolyte					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	112315-1, 112315-2					
	Preparation	Tested concentration: LCL Dilution: Ready-to-use Diluent: NA					
Soil load		OECD 3-part soil load					
Carrier type, # per lot		Glass petri dishes, 1					
Test conditions		Contact time	2 minutes	Temp	26.5-27.1°C	RH	48-50%
Testing Lab, Lab Study ID		Antimicrobial Test Laboratories, GLP1343					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		<p>Carrier dry temperature: 9.0-11.5°C</p> <p>On 11/25/15, Influenza Infection Medium without bovine serum albumin was used for application to plate recovery control carriers and for application of cell culture media following plating of viral titrations.</p> <p>On 11/25/15, the Sephacryl column used for neutralization of test lot 112315-2 was run through the centrifuge twice because the column slipped on the first run, preventing recovery of the full elute volume.</p>					

IV STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log ₁₀ TCID ₅₀ /carrier)
			112315-1	112315-2	
2 minutes, ready-to-use, 3-part soil load					
50390001	Bovine Viral Diarrhea Virus, Strain NADL (ATCC VR-1422)	10 ⁻¹ to 10 ⁻⁶ dilution	Complete inactivation *	Complete inactivation *	6.43**
		Log ₁₀ TCID ₅₀ /carrier	≤1.80*	≤1.80*	
		Log Reduction	≥4.63**	≥4.63**	
50288202	Influenza A (H1N1), Strain A/Virginia/ATCC 1/2009 (ATCC VR-1736)	10 ⁻¹ to 10 ⁻⁸ dilution	Complete inactivation	Complete inactivation	4.80
		Log ₁₀ TCID ₅₀ /carrier	≤1.80	≤1.80	
		Log Reduction	≥3.00	≥3.00	

*Same result for both replicates.

**Average of two replicates (6.80 and 6.05 log₁₀ TCID₅₀).

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50390001	Disinfectant, virucidal	Hard, non-porous surfaces	Liquid, RTU	2 minutes	OECD 3-part soil load	NA	Bovine Viral Diarrhea Virus, Strain NADL (ATCC VR-1422)	Yes
50288202	Disinfectant, virucidal	Hard, non-porous surfaces	Liquid, RTU	2 minutes	OECD 3-part soil load	NA	Influenza A (H1N1), Strain A/Virginia/ATCC1/2009 (ATCC VR-1736)	Yes

VI LABEL COMMENTS

Label Date/Identification Number: Revised proposed label dated 9/1/2017

1. The proposed label claims that the ready-to-use product, Excelyte Vet, when applied as a liquid, is an effective one-step disinfectant with virucidal activity on hard, non-porous surfaces at a 2 minute contact time against the following:

Human Hepatitis C Virus as Bovine Viral Diarrhea Virus, Strain NADL (ATCC VR-1422)
Influenza A (H1N1), Strain A/Virginia/ATCC1/2009 (ATCC VR-1736)

These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the ready-to-use product, Excelyte Vet, when applied as a liquid, is an effective one-step disinfectant with virucidal activity on hard, non-porous surfaces at a 10 minute contact time against the following:

Adenovirus 1, Strain 71 (ATCC VR-1)
Norovirus or Norwalk Virus as Feline Calicivirus, Strain F-9 (ATCC VR-782)
Respiratory Syncytial Virus, Strain A-2 (ATCC VR-1540)
Rhinovirus 16, Strain 11757 (ATCC VR-283)
Rotavirus (Group A), Strain WA (ATCC VR-2018)

These claims are **acceptable** as they are supported by data reviewed in support of Ecaflo Anolyte (Reg. No. 82341-1) in DP# 428914.

3. The proposed label claims that the ready-to-use product, Excelyte Vet, when applied as a liquid, is an effective one-step disinfectant with fungicidal activity on hard, non-porous surfaces at a 10 minute contact time against the following:

Candida albicans (ATCC 10231)

These claims are **acceptable** as they are supported by data reviewed in support of Ecaflo Anolyte (Reg. No. 82341-1) in DP# 428914.

4. Make the following changes to the proposed label:
 - i. On pages 1 and 2, the claim that the product is an “aqueous solution of sodium chloride” is misleading because the active ingredient is in fact hypochlorous acid. Clarify this claim.
 - ii. On page 5:
 - a. Change “*Klebsiella pneumonia*” to “*Klebsiella pneumoniae*.”
 - b. Remove “leading” from “((leading) causative agent of) the common cold.”
 - c. Remove “(the virus that) causes diarrhea.”
 - d. Add “virus” after “Canine distemper” and “Influenza A (H1N1).”
 - e. Remove “(representative of) the common” from the Influenza viruses.
 - f. Remove “cause of respiratory infection in infants.”
 - iii. On page 7, in the directions “[To] Sanitize [Hard, Non-Porous] [Food Contact] Surfaces”, clarify that exterior surfaces of coolers, refrigerators, freezers,

microwave ovens, ovens, and stove tops should be allowed to come to room temperature before sanitization.

- iv. On page 9, the directions for use “[To] Use as a Hand Dip [Glove Dip or Boot Wash]” are not substantiated by efficacy data accepted by the Agency. A minimum concentration of 200 ppm FAC is supported by accepted data for food contact sanitization of inanimate hard, non-porous surfaces (MRID 48992830 reviewed in support of Ecaflo Anolyte (Reg. No. 82341-1) in DP# 407169). This data does not support use directly on skin, which is not an EPA-regulated use. Change the directions to require a 1:1.5 dilution for a 200 ppm FAC (or more concentrated) solution. Remove all references to use of the product as a “hand dip.”
- v. On page 10:
 - a. Remove all references to the product as a “Hospital Grade” or “Veterinarian Grade” disinfectant. These claims imply heightened efficacy.
 - b. Remove “- and/or – sanitizer” from the claim “Broad spectrum disinfectant – and/or – sanitizer.” The Agency has not defined a “broad spectrum” sanitizer.
 - c. Remove or limit the claim “Assures proper strength, product effectiveness and standardizes technique.” The directions for use indicate that the product is only ready-to-use for disinfection applications, but should be diluted for sanitization and other applications. However, the product is not automatically diluted, nor are measuring devices provided. In addition, the product may be applied with several tools (e.g. “cloth, wipe, mop or sponge”) as a liquid or as a spray, which indicates that behavioral factors are also important to standardize technique.
 - d. Remove “[are broadly antiviral and capable of inactivating both enveloped and non-enveloped Viruses*].” The Agency has not defined a “broadly antiviral” claim.
- vi. On page 11:
 - a. Remove “Fast acting disinfectant.” Contact times of 2 or 10 minutes are not “fast.” The Agency’s definition of a “fast” contact time is 30 seconds or less.
 - b. Remove “Kills – or Effective against Distemper” and “...Kennel Cough.” Claims to treat or control disease are not allowed on FIFRA labels.
 - c. Change “from” to “spores on” in the claims “Reduces Clostridium difficile...from treated surfaces.”
 - d. Remove “A New Generation of Protection.” The claim implies heightened efficacy.
 - e. Remove references to “common” bacteria and/or viruses. The Agency has not defined “common” organisms.
- vii. On page 12:
 - a. Qualify “Pseudomonacidal” and “Staphylocidal” with the names of the organisms to which they refer.
 - b. Clarify the claims “Ready-to-Use [Formula]” and “No mixing required.” The directions for use require dilution of the product for some uses.
 - c. Remove “The simple solution to – or – for a healthier home.” The claim implies both heightened efficacy and disease control.

- viii. On pages 14-16, in Tables 2 and 3 under the heading “HARD, NON-POROUS SURFACES”, clarify that the product is to be used only on exterior surfaces of complex medical and dental equipment such as CPAP machines, dialysis machines, and dental chairs.
- ix. On pages 17-19 (Table 4):
 - a. Remove “Cleaning In Place [CIP].” There are no directions for use for cleaning in place.
 - b. Change “Tee” to “Tea”
 - c. Remove all items from the list of hard, non-porous surfaces that are not food service items (e.g. dental equipment, musical instruments, e-cigarettes, etc.).